K032155

MAY - 7 2004

X. PREMARKET NOTIFICATION SUMMARY

Submitted by:

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SWEDEN

Contact Person:

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Mr. Gary L. Yingling
Mr. Michael H. Hinckle
Kirkpatrick & Lockhart, LLP
1800 Massachusetts Avenue, NW
Washington, DC 20036-1800

Date Prepared: July 10, 2003

Trade Name: G-ThawKit Blast™

Common Name: Assisted Reproduction Media

Classification Name: Reproductive Media and Supplements (21 C.F.R. § 884.6180)

Predicate Device: Blastocyst Thaw Media Kit (K000309)

Description of the Device: MOPS buffered media. For use in sequence after the addition of G-MM™ or HSA-solution™ and pre-equilibration at +20 ± 5°C and ambient atmosphere.

Intended Use: Medium for *In Vitro* Fertilization Procedures

Indications for Use: Media for thawing of blastocyst stage embryos

Technological Characteristics:
The technological characteristics of G-ThawKit Blast™ are similar to those of the predicate device. Some modifications were made to improve the performance of the device. The G-ThawKit Blast™ contains three thawing solutions. Two of the solutions contain Glycerol which has been included to improve a slow diffusion of Glycerol out of the cells. In combination with G-FreezeKit Blast™ , the thawing solutions provide an equal concentration gradient of Glycerol and Sucrose in a step up - step down protocol for freezing and thawing of human blastocysts. The G-ThawKit Blast™ also contains Penicillin G as antibiotic instead of Gentamicin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vitrolife Sweden AB
% Gary L. Yingling, Esq.
Consultant
Kirkpatrick & Lockhart, L.L.P.
1800 Massachusetts Avenue, NW
WASHINGTON DC 20036-1800

Re: K032155
Trade/Device Name: G-ThawKit Blast™ - Assisted Reproductive Media
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: February 19, 2004
Received: February 23, 2004

Dear Mr. Yingling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032155

Device Name: G-ThawKit Blast™
Assisted Reproduction Media

Indications For Use: Media for thawing of blastocyst stage embryos

Prescription Use __x____ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032155